(d) The opposing party may file a brief of no greater length than that allowed for the posthearing brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief, unless such time period is extended by the Commissioner or the entity designated by the Commissioner to hear appeals on request of the opposing party for good cause shown. Any brief in opposition to exceptions shall be filed with the Division of Dockets Management and the DAB (addresses above).

(e) The appellant may file a reply brief not more than 10 pages in length within 10 days of being served with appellee's brief.

(f) There is no right to appear personally before the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB).

(g) The entity deciding the appeal will consider only those issues raised before the presiding officer, except that the appellee may make any argument based on the record in support of the initial decision or decision granting summary decision.

(h) If on appeal the entity deciding the appeal considers issues not adequately briefed by the parties, the entity may ask for additional briefing. However, no such additional briefs will be considered unless so requested.

(i) If any party demonstrates to the satisfaction of the entity deciding the appeal (currently the DAB) that additional evidence not presented at the hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at the hearing, the entity deciding the appeal may remand the matter to the presiding officer for consideration of the additional evidence.

(j) The Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) will issue a decision on the appeal within 60 days, if practicable, of the due date for submission of the appellee's brief. In the decision, the entity deciding the appeal may decline to review the case, affirm the initial decision or decision granting summary decision (with or without an opinion), or reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined by the presiding officer in the initial decision. If the entity deciding the appeal declines to review the case, the initial decision or the decision granting summary decision shall constitute the final decision of FDA and shall be final and binding on the parties 30 days after the declination by the entity deciding the appeal.

(k) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

[60 FR 38626, July 27, 1995, as amended at 71 FR 5979, Feb. 6, 2006]

§ 17.48 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the presiding officer or by any of the parties is grounds for vacating, modifying, or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the presiding officer or the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) to be inconsistent with substantial justice. The presiding officer and the entity deciding the appeal at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

§ 17.51 Judicial review.

(a) The final decision of the Commissioner of Food and Drugs or other entity deciding the appeal (currently the DAB) constitutes final agency action from which a respondent may petition for judicial review under the statutes governing the matter involved. Although the filing of a petition for judicial review does not stay a decision under this part, a respondent may file a petition for stay of such decision under § 10.35 of this chapter.

(b) The Chief Counsel of FDA has been designated by the Secretary of

Health and Human Services as the officer on whom copies of petitions for judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the entity deciding the appeal (currently the DAB).

(c) Exhaustion of an appeal to the entity deciding the appeal (currently the DAB) is a jurisdictional prerequisite to judicial review.

§ 17.54 Deposit in the Treasury of the United States.

All amounts assessed pursuant to this part shall be delivered to the Director, Division of Financial Management (HFA–100), Food and Drug Administration, rm. 11–61, 5600 Fishers Lane, Rockville, MD 20857, and shall be deposited as miscellaneous receipts in the Treasury of the United States.

PART 19—STANDARDS OF CONDUCT AND CONFLICTS OF INTEREST

Subpart A—General Provisions

Sec.

Subpart B—Reporting of Violations

Subpart C—Disqualification Conditions

AUTHORITY: 21 U.S.C. 371.

SOURCE: 42 FR 15615, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 19.1 Scope.

This part governs the standards of conduct for, and establishes regulations to prevent conflicts of interest by, all Food and Drug Administration employees.

§ 19.5 Reference to Department regulations.

(a) The provisions of 45 CFR part 73, establishing standards of conduct for all Department employees, are fully applicable to all Food and Drug Administration employees, except that such regulations shall be applicable to special government employees, i.e., consultants to the Food and Drug Administration, only to the extent stated in subpart L of 45 CFR part 73.

(b) The provisions of 45 CFR part 73a supplement the Department standards of conduct and apply only to Food and Drug Administration employees except special government employees.

§ 19.6 Code of ethics for government service.

The following code of ethics, adopted by Congress on July 11, 1958, shall apply to all Food and Drug Administration employees:

CODE OF ETHICS FOR GOVERNMENT SERVICE

Any person in Government service should:

1. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.

2. Uphold the Constitution, laws, and legal regulations of the United States and of all governments therein and never be a party to their evasion.

3. Give a full day's labor for a full day's pay; giving to the performance of his duties his earnest effort and best thought.

4. Seek to find and employ more efficient and economical ways of getting tasks accomplished.

5. Never discriminate unfairly by the dispensing of special favors or privileges to anyone, whether for remuneration or not; and never accept, for himself or his family, favors or benefits under circumstances which might be construed by reasonable persons as influencing the performance of his governmental duties.

6. Make no private promises of any kind binding upon the duties of office, since a Government employee has no private word which can be binding on public duty.

7. Engage in no business with the Government, either directly or indirectly, which is inconsistent with the conscientious performance of his governmental duties.

8. Never use any information coming to him confidentially in the performance of governmental duties as a means for making private profit.

9. Expose corruption wherever discovered.

10. Uphold these principles, ever conscious that public office is a public trust.